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Louis H. Weinstein (LW 7868)
BUDD LARNER, P.C.
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Short Hills, New Jersey 07078
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Attorneys for Defendants and
Counterclaim Plaintiffs
Dr. Reddy's Laboratories, Ltd. and
Dr. Reddy's Laboratories, Inc.

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE and ASTRAZENECA LP, KBI INC. and KBI-E, INC.,	07-CV-6790 (CM)(GWG)
Plaintiffs and Counterclaim Defendants,	**Portions Filed Under Seal**
v.	**(Exhibits 19 and 20 contain Confidential DRL Information)**
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.	**ELECTRONICALLY FILED**
Defendants and Counterclaim Plaintiffs.	

THIRD DECLARATION OF LOUIS H. WEINSTEIN
(FILED IN SUPPORT OF DRL'S MOTION FOR SUMMARY JUDGMENT)

I, LOUIS H. WEINSTEIN, declare that the following is true and correct:

1. I am the same Louis H. Weinstein who submitted the Second Declaration of Louis H. Weinstein (Filed In Support of DRL's Motion For Summary Judgment) ("2nd Weinstein Declaration"). The instant Declaration ("3rd Weinstein Declaration") is also filed in support of DRL's Motion for Summary Judgment. The Exhibits to the 2nd Weinstein Declaration were

numbered from Exhibit 1 to Exhibit 18. For the sake of clarity and the Court's convenience, I begin the numbering of the Exhibits to the instant 3rd Weinstein Declaration with "Exhibit 19". Thus, a reference to "DRL Ex. __" means a reference to the corresponding Exhibit to either the 2nd Weinstein Declaration (DRL Exhibits 1-18) or the instant 3rd Weinstein Declaration (DRL Exhibits 19-32). The statements in this 3rd Weinstein Declaration and the 2nd Weinstein Declaration are based on my personal knowledge.

2. I am lead counsel for Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL") in this litigation.

3. The parties received the Court's Rulings on Astra-Zeneca's Request for Infringement Discovery (the "Court's Rulings") on May 5, 2008. DRL Ex. 14.

4. The morning after receiving the Court's Rulings, I sent a letter to Astra's counsel by facsimile to confirm that, consistent with the parties' prior agreement concerning the use of confidential DRL information, the confidential DRL information to be produced pursuant to the Court's Rulings would only be used to determine whether DRL infringed the two patents in suit. A true and accurate copy of my May 6, 2008 letter to Mr. Errol Taylor is attached hereto as Exhibit 26.

5. Late in the day on May 7, 2008, Astra's counsel sent me a letter by facsimile asking DRL to produce the additional information called for in the Court's Rulings by the close of business on May 9, 2008. Astra's counsel did not agree that DRL's confidential information would only be used to determine whether DRL infringed the two patents in suit. A true and accurate copy of Mr. John Griem's letter of May 7, 2008, and the 13 page proposed Protective Order attached thereto, is attached hereto as Exhibit 27.

6. During the day on May 8, 2008, I sent Magistrate Maas a letter by facsimile asking for the Magistrate's assistance in "expediting" DRL's production of the confidential DRL information called for in the Court's Rulings. In my letter I asked Magistrate Maas to order Astra only to use DRL's confidential information for the purpose of determining infringement of the patents in suit. A true and accurate copy of Louis H. Weinstein's May 8, 2008 letter to Magistrate Maas is attached hereto as Exhibit 28.

7. Counsel for Astra wrote a letter to Magistrate Maas on May 9, 2008. At page 3 of the letter counsel for Astra argued that Astra should not be limited to using DRL's confidential information solely for the purpose of determining infringement of the patents in suit. A true and accurate copy of John Griem's May 9, 2008 letter to Magistrate Maas is attached hereto as Exhibit 29.

8. On May 13, 2008, counsel for Astra agreed in an e-mail to accept DRL's confidential information pursuant to the restrictions in my May 6, 2008 letter, while reserving the right to raise the appropriateness of those restrictions and the other issues briefed with Magistrate Maas, with a new magistrate, or Judge McMahon. A true and accurate copy of the May 13, 2008 e-mail from Mr. Griem is attached hereto as Exhibit 30.

9. After receiving the e-mail, on May 13, 2008 my firm produced to Astra's counsel via Federal Express next day delivery a CD containing the responsive documents to Astra's Document Requests Nos. 1 and 2. The produced documents bore production numbers DRL0001 to DRL03647.

10. Late in the afternoon on Friday May 16, 2008, counsel for Astra complained in an e-mail to me that DRL's production was incomplete. A true and accurate copy of the May 16, 2008 e-mail is attached hereto as Exhibit 31.

11. In the May 16, 2008 e-mail, counsel for Astra complained that DRL's "ANDA and DMF production is incomplete." According to the e-mail from Astra's counsel, "[t]he Court ordered DRL to produce 'full and entire versions of the ANDA paperwork and the DMF files that were submitted by DRL to the Food and Drug Administration.'" DRL Ex. 31.

12. On Monday May 19, 2008 and Tuesday May 20, 2008 I had telephone conversations with Astra's counsel concerning Astra's complaint about DRL's ANDA and DMF production. I pointed out to Astra's counsel that I did not think the Court had ordered DRL to produce its entire ANDA and DMF. Rather, I told Astra's counsel that I believed the Court had ordered DRL to produce the full and entire versions of the materials "as requested in Document Request No. 1 and 2" and that I believed these requests were limited by Astra to the Chemistry, Manufacturing, and Controls ('CMC') section" of the ANDA (Document Request No. 1) and certain specified "[p]ortions" of the DMF (Document Request No. 2), as well as supplements and amendments. A true and accurate copy of Astra's Document Requests is attached hereto as Exhibit 25.

13. I had another telephone conversation with Astra's counsel on May 20, 2008. As a result of the May 19 and May 20 conversations I reached agreement with Astra's counsel that the production of certain additional documents would resolve all discovery disputes in advance of the deposition scheduled for May 23, 2008. Based on that I agreement I sent counsel for Astra an e-mail with PDF files corresponding to documents bearing production numbers DRL 03648 to DRL03871. A copy of the confirmatory e-mail that I sent Astra's counsel on May 20, 2008 is attached hereto as Exhibit 32.

14. Copies of documents produced to Astra's counsel bearing production numbers DRL00001 to DRL02971 and DRL03855 to DRL03871 are attached hereto as Exhibit 19.

Kumara Sekar, Ph.D., in his Declaration filed herewith, has certified that these documents are true and accurate copies of documents submitted by DRL to the FDA in ANDA No. 78-878. Sekar Decl. ¶ 6.

15. Copies of documents produced to Astra's counsel bearing production numbers DRL02972 to DRL03854 are attached hereto as Exhibit 20. Kumara Sekar, Ph.D., in his Declaration filed herewith, has certified that these documents are true and accurate copies of documents submitted by DRL to the FDA in DMF No. 17706. Sekar Decl. ¶ 6.

16. Exhibit 21 hereto is a true and accurate copy of the Declaration of Per Lindberg from the prosecution history of U.S. Patent Application Serial No. 08/313,342.

17. Exhibit 22 hereto is a true and accurate copy of the Office Action Summary dated January 27, 1998 from the prosecution history of U.S. Patent Application Serial No. 08/313,342.

18. Exhibit 23 hereto is a true and accurate copy of the Amendment dated July 31, 1998 from the prosecution history of U.S. Patent Application Serial No. 08/313,342.

19. Exhibit 24 hereto is a true and accurate copy of the marked up original claims from the prosecution history of U.S. Patent Application Serial No. 08/313,342.

20. Exhibit 25 hereto is a true and accurate copy of Astra's November 19, 2007 Document Requests in the present litigation.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge, information and belief.

Dated: August 13, 2008

By: Lou Weinstein
Louis H. Weinstein

BUDD LARNER P.C.
150 John F. Kennedy Parkway
Short Hills, New Jersey 07078
(973) 379- 4800

Attorneys for Defendants and Counterclaim-Plaintiffs
Dr. Reddy's Laboratories, Ltd. and
Dr. Reddy's Laboratories, Inc.

CERTIFICATE OF SERVICE

I certify that on this 13th day of August 2008, I caused a true and correct copy of the foregoing:

THIRD DECLARATION OF LOUIS H. WEINSTEIN
(FILED IN SUPPORT OF DRL'S MOTION FOR SUMMARY JUDGMENT)

to be served upon counsel for AstraZeneca in the following manner:

By Federal Express

Errol B. Taylor, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1 Chase Manhattan Plaza
New York, New York 10005-1413
Telephone: 212-530-5000
Facsimile: 212-530-5219

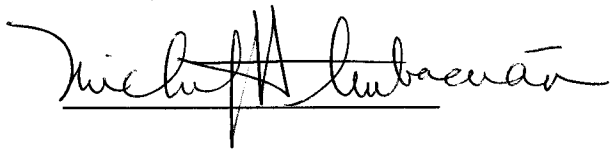


EXHIBIT 19

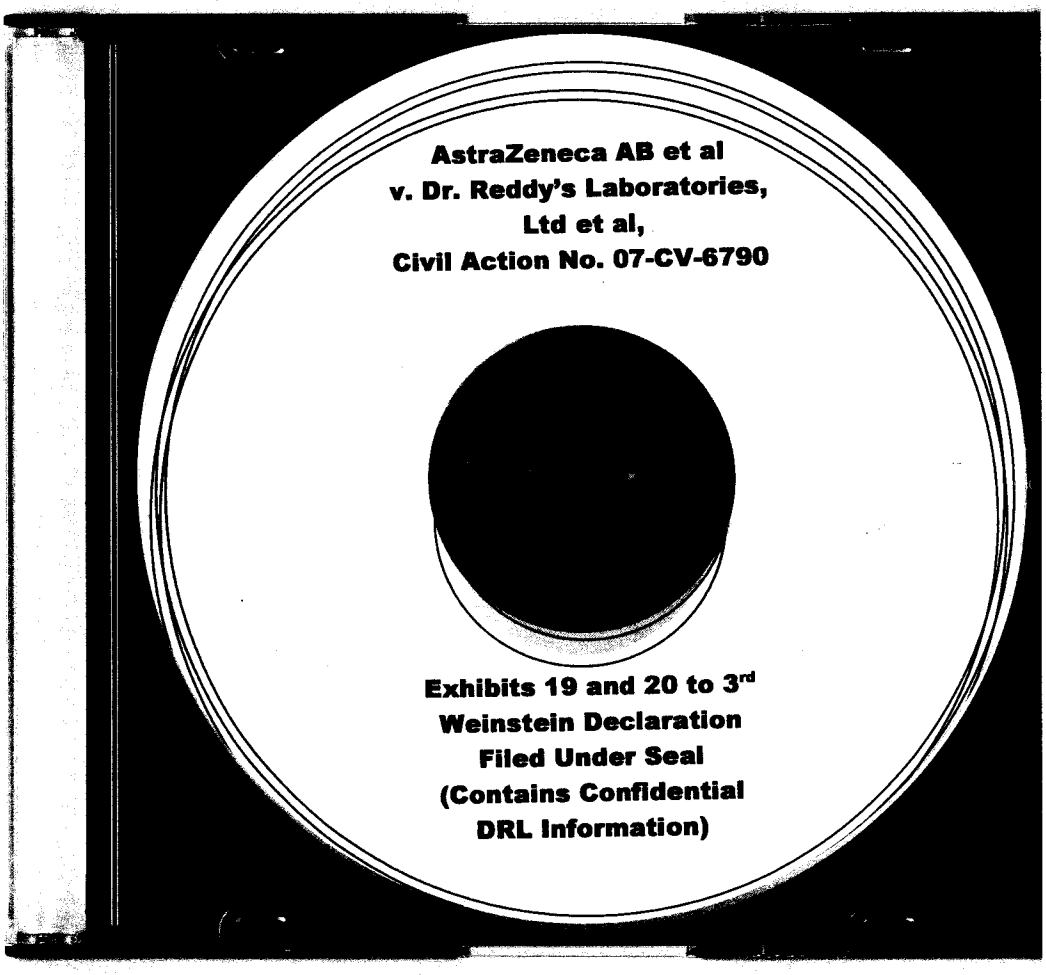
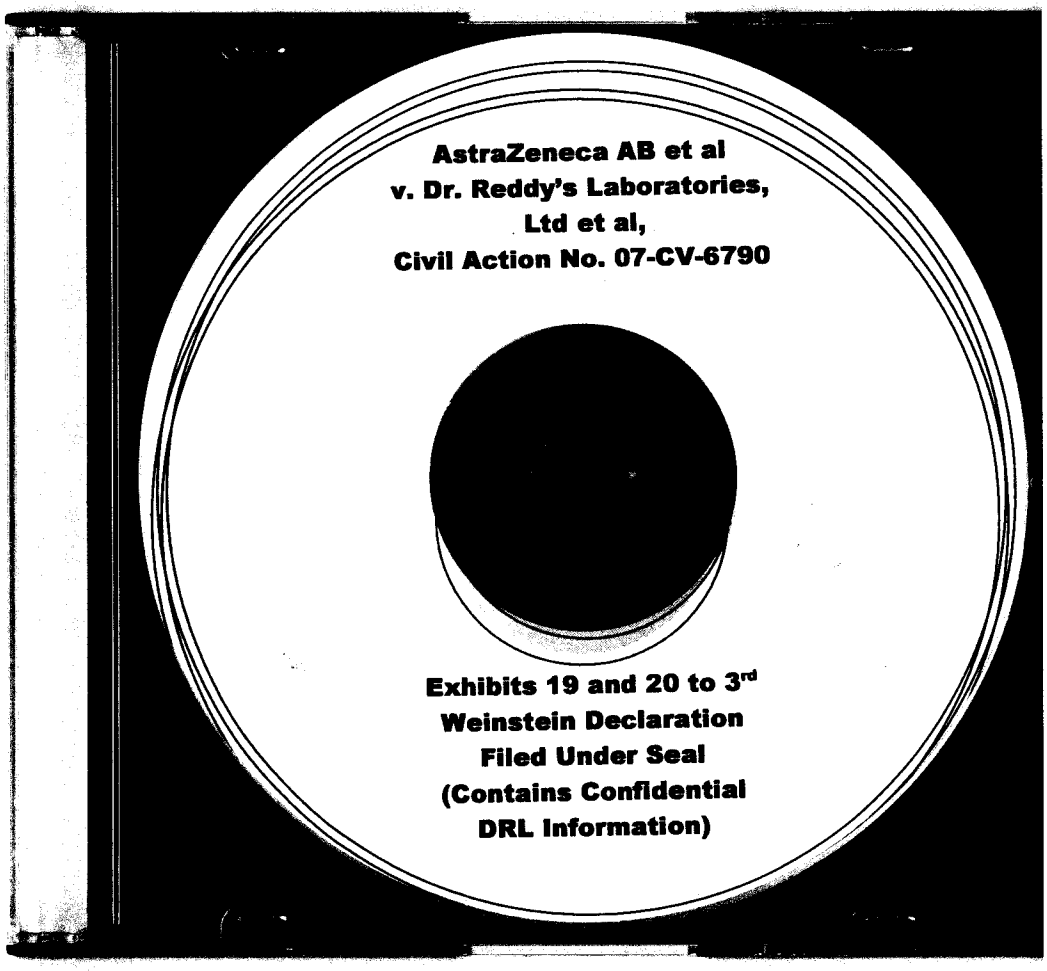

AstraZeneca AB et al
v. Dr. Reddy's Laboratories,
Ltd et al,
Civil Action No. 07-CV-6790
Exhibits 19 and 20 to 3rd
Weinstein Declaration
Filed Under Seal
(Contains Confidential
DRL Information)

EXHIBIT 20


AstraZeneca AB et al
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Ltd et al,
Civil Action No. 07-CV-6790
Exhibits 19 and 20 to 3rd
Weinstein Declaration
Filed Under Seal
(Contains Confidential
DRL Information)

EXHIBIT 21

1103326-0109

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Källström et al.
Serial No.	: 08/313,342
Filed	: September 27, 1994
For	: A NOVEL COMPOUND FORM
Examiner	: J. Fan
Group Art Unit	: 1612

transmitted by facsimile to the

I hereby certify that this paper is being ~~deposited with the United States Postal Service as first class mail in an envelope addressed to~~ Assistant Commissioner for Patents Washington, D.C. 20231 on October 1, 1998

John M. Genova — Attorney Name — 32,224 PTO Reg. No.

John M Genova — Signature — October 1, 1998 Date of Signature

Commissioner of Patents and Trademarks
Washington, D.C. 20231

DECLARATION OF PER LINDBERG

Sir:

I, Per Lennart Lindberg, of Gundas Gata 40, Mölndal, Sweden, declare and say:

1. I am the Head of the Preclinical Alliances Group of Astra Hässle AB ("Hässle"). I have held this position since 1996. Hässle is a member of Astra AB ("Astra"), the assignee of the referenced application. I joined Hässle in 1982 as a Group Leader of the medicinal chemistry group that actually performed the research of omeprazole and related compounds. In general, my

professional career has been concentrated in the technical areas of organic chemistry, medicinal chemistry and pharmacology. I obtained my Ph.D. in Organic Chemistry in 1977 from the University of Lund in Sweden. I have published extensively in the areas of organic chemistry, medicinal chemistry and pharmacology. I am a named inventor of at least twenty-nine patents and patent applications. A copy of my curriculum vitae is attached hereto.

2. Omeprazole, originating from Hässle, is a well-known gastric-acid secretion inhibitor currently used for the prevention and treatment of gastric acid related disorders and gastrointestinal inflammatory diseases, e.g., gastritis, gastric ulcer and duodenal ulcer. Omeprazole is a gastric acid-pump inhibitor and it has proved to have an unusually high clinical efficacy. I am familiar with and fully understand the chemistry and biology of omeprazole.

3. I have read and fully understand the disclosure and claimed invention of the referenced U.S. Patent Application Serial No. 08/313,342 (the "'342 application"). The invention of the '342 application is directed to a magnesium omeprazole salt having a degree of crystallinity which is greater than 70% as measured by X-ray powder diffraction and to a process for making this novel form of magnesium omeprazole salt.

4. I have been informed by counsel for Applicants that U.S. Patent No. 4,738,974 to Brändström (the "'974 patent") has been cited as prior art against the '342 application. I have read and fully understand the disclosure and claimed invention of the '974 patent. The '974 patent claims alkaline salts of omeprazole. The named assignee of the '974 patent is Hässle. The experimental work underlying the invention of the '974 patent was completed under my

supervision. Specifically, I was the Group Leader of the department that conducted the research which lead to the claimed invention of the '974 patent.

5. Crystals of magnesium omeprazole salts are very fragile thereby making processes utilizing such crystals in full scale production less attractive. Accordingly, the problem addressed by the inventors was the recovery and work-up of crystals of a magnesium omeprazole salt that could be used, notwithstanding a fragile crystalline structure, in full scale manufacturing processes, including the production of the magnesium omeprazole salt itself. In fact, the impetus for the claimed invention came when chemists belonging to the Astra group demonstrated that the processes disclosed in the '974 patent were not suitable for the full scale production of crystals of magnesium omeprazole salts and that the magnesium omeprazole salts made according to that patent were less suitable for pharmaceutical formulations.

6. It was completely unexpected, therefore, when the inventors of the subject invention discovered that a magnesium omeprazole salt having a high degree of crystallinity could be recovered after a controlled crystallization step in aqueous alcohol and that this salt was more suitable and, hence, preferred for use in full scale production. According to the invention, inorganic salts are separated from the mother liquor prior to the addition of water to form crystals of magnesium omeprazole. Advantageously, the products of the inventive process are characterized by a degree of crystallinity of not less than 70%, preferably higher than 75%, as determined by X-ray powder diffraction. Moreover, the product possesses a higher degree of purity and is more stable to decomposition. Example 1 on page 6 of the '342 application

illustrates the claimed process on a full manufacturing scale and indicates the resulting magnesium omeprazole salt had a degree of crystallinity of 76% as determined by X-ray powder diffraction.

7. The '974 patent claims alkaline salts of omeprazole. Example 6 of that patent is directed to the preparation of a di-omeprazole magnesium salt. The product of this Example 6 is described as a "crystalline" solid having a melting point of 178-180°. Neither Example 6 nor the remainder of the specification indicates whether the product of that example was analyzed to determine the presence of a crystalline structure or the degree of crystallinity. Rather, having supervised the research underlying the '974 patent and reviewed the data supporting the '794 patent, I can state that the product of Example 6 was examined visually. On the basis of a visual inspection and the detection of a narrow melting point range of 178-180°, the product of Example 6 gave the appearance of a "crystalline" solid and it was reported as such by the research team. Thus, at the time of the invention of the '974 patent, there was never any analytical determination of either a crystalline structure or the degree of crystallinity of the product of Example 6.

8. Counsel for Applicants provided me with a copy of the Office Action (Paper No. 15), mailed February 3, 1998, which issued in the referenced application. On page 4 of the Office Action, the Examiner states that the "[m]agnesium omeprazole salt prepared as in Example 6 of the art should be compared with the [m]agnesium salt of omeprazole prepared in the instant application". It is my understanding that the '974 patent represents the art to which reference is made in the preceding quote from the Office Action.

9. At the direction of counsel for the Applicants, Applicants completed repeat experiments based on Example 6 of the '974 patent and are in the process of conducting stability testing up to three months with regard to the products of the repeat experiments based on Example 6 of the '974 patent and the claimed magnesium omeprazole salt of the '342 application. I supervised and fully understand the protocol and results of the repeat experiments and comparative studies as described below in Paragraphs 11, 12 and 13 of my Declaration. At the time of the submission of this Declaration, the results of the stability testing at three months were not available for the products of the repeat experiments described in Paragraphs 12B and 12C. Nevertheless, as demonstrated below, the comparative data obtained after one month is sufficient to make conclusive and valid statements regarding the advantageous and unexpected degree of improved storage stability which distinguishes the claimed magnesium omeprazole salt.

10. In view of my supervisory role in the research underlying the '974 patent, I consider myself to be qualified to discuss the disclosure of the '974 patent and to interpret the results of the repeat experiments and comparative data pertaining to Example 6 of the '974 patent. Based on the data set forth below and the information available to me in my past and present positions at Hässle, it is my opinion that the product of Example 6 of the '974 patent is more accurately described as a solid amorphous compound. As such, the product of Example 6 of the '974 patent is less suitable for use in the full scale production of pharmaceutical substances. Thus, the product of Example 6 of the '974 patent does not suggest the improved magnesium omeprazole salt of the claimed invention.

Repeat Experiment of Example 1 of the Subject '342 Application: Experimental Method

11. The same experimental method was followed as described in Example 1, page 6, of the original specification of the '342 application except that the following quantities of reactants were employed: 3,400 liters of methanol; 7.0 kg of magnesium; 1.7 liters of CII_2Cl_2; 168 kg of omeprazole; and 1,500 liters of water. The recovered magnesium omeprazole salt product weighed 155.2 kg and was 97% crystalline as determined by X-ray powder diffraction.

Repeat Experiments of Example 6 of the '974 Patent: Experimental Methods

12A. Magnesium (1.77 g) was reacted with methanol (50 ml) in the presence of three drops of CCl_4 in a 250 ml flask. Heat was applied to the reaction mixture for 1 hour and 15 minutes until no more gas evolved and the magnesium had completely reacted to give a solution of $Mg(OCH_3)_2$. More methanol (50 ml) was added to the solution. The $Mg(OCH_3)_2$ solution was added to a suspension of omeprazole (50.0 g) in methanol (1000 ml) in a 2000 ml three necked flask during a period of 20 minutes. The resulting pale yellow mixture was stirred for another 10 minutes at room temperature and the solvent was then evaporated. The solid product was determined by X-ray powder diffraction to be a crystalline substance. The particle size of the bimodal product was approximately 100 μm as determined by laser diffraction technique. The product had a methanol content of 22% as determined by gas chromatography.

12B. Omeprazole (10.0g, 29 mmol) was suspended in 200 ml of methanol. In a separate flask, magnesium (0.35 g, 14.4mmol) was mixed with methanol (10 ml) and one drop of CCl_4. After 5 hours, the magnesium had completely reacted with the methanol to give a cloudy gray $Mg(OCH_3)_2$ solution. More methanol (10 ml) was added to the suspension of omeprazole. The

$Mg(OCH_3)_2$ solution was then added drop-wise under stirring to the suspension of omeprazole in methanol. The addition took approximately 15 minutes. The mixture was stirred at room temperature for 30 minutes. Evaporation of the solvent of the slightly colored mixture gave an orange syrup which was solidified to give an amorphous solid material as determined by X-ray powder diffraction.

12C. Magnesium (0.35 g) was reacted with methanol (10 ml) in the presence of one drop of CCl_4 in a 100 ml three necked flask. The reaction mixture was heated until the magnesium had completely reacted to give a solution of $Mg(OCH_3)_2$. The $Mg(OCH_3)_2$ solution was added to a suspension of omeprazole (10.0 g) in methanol (200 ml) in a 500 ml three necked flask and the resulting solution had a cloudy, pale yellow color. Evaporation gave a pale pink-brown substance. The substance was amorphous as determined by X-ray powder diffraction.

Comparative Data: Stability Testing

13. The storage stability of each of the products of repeat experiments 12A, 12B and 12C, above, and the magnesium omeprazole salt prepared in accordance with the claimed invention (See ¶11, above) was tested after open air storage up to three months at 50°C and 40°C/75% relative humidity. The omeprazole degradation products and process impurities were analyzed by a reversed phase high performance liquid chromatographic system. The octadecyl derivatized silica gel microsphere C_{18}, 3µm average bead size, was used as the stationary phase. The mobile phase consisted of a phosphate buffer pH 7.4 and acetonitrile 26% and $TBAHSO_4$ as counter ion ($TBAHSO_4$ = tetrabutylammonium hydrogen sulfate). The amount of eluted degradation products and process impurities were detected by UV at 280 nm. Solution color was estimated by

measuring absorbance of a filtered 2% solution in methanol in a 1 cm cell at 440 nm. The results are shown in the following Table 1:

TABLE 1

STORAGE STABILITY OF MAGNESIUM OMEPRAZOLE SALTS						
	Appearance		Absorbance (440 nm)		Degradation Products (%)	
	50°C	40°C 75% relative humidity	50°C	40°C 75% relative humidity	50°C	40°C 75% relative humidity
¶11 Product = '342 Application (97% crystallinity)						
0-analysis			0.01		0.09	
1 month	light yellow	light yellow	0.04	0.04	0.10	0.07
3 months	light yellow	light pink	0.07	0.07	0.26	0.12
¶12A Product (crystalline solid, 22% methanol content)						
0-analysis			not soluble in methanol		0.13	
1 month	yellow-beige	beige	not soluble in methanol		0.19	0.28
3 months	yellow-beige	beige	not soluble in methanol		0.39	0.42
¶12B Product (amorphous solid)						
0 analysis	red-brown color		0.25		0.52	
1month			0.26	0.34	1.62	1.26
3 months						
¶12C Product (amorphous solid)						
0-analysis	inhomogenous, beige with dark spots		0.05		0.04	
1 month			0.06	0.15	0.88	0.43
3 months						

Discussion

14. As stated in Paragraph 6 of my Declaration, above, the process of the '342 application is characterized by a controlled crystallization step. Inorganic salts are separated from the mother liquor prior to the addition of water to crystallize magnesium omeprazole. A further distinguishing feature of the claimed process is the use of an aqueous alcohol solvent, e.g., methanol, to put omeprazole in solution and the subsequent use of a different solvent, i.e., water, to recover the crystalline magnesium omeprazole salt from solution. In contrast, the respective process of Example 6 of the '974 patent and of the repeat experiments 12A-C, above, use methanol as the sole solvent throughout the process. The use of different solvents as part of the controlled crystallization step of the '342 application is an important contribution to the recovery of the inventive crystals of magnesium omeprazole salt. Owing to the relatively higher degree of crystallinity, the use of these crystals as pharmaceutical substances in large scale manufacturing processes is preferred.

15. The products of the repeat experiments 12A-C, above, are less suitable as pharmaceutical substances. The products of repeat experiments 12B and C were analyzed by X-ray powder diffraction and were determined to be amorphous solids. Additionally, at page 7, lines 7-25, of the '342 application, there is a discussion of the crystallinity of a magnesium omeprazole product prepared by a prior art method of reacting omeprazole with $Mg(OCH_3)_2$. The product is identified as "sample B" and is reported to have 0% crystallinity. The process for making this sample B corresponds to the process of Example 6 of the '974 patent. Thus, in three repeat experiments based on Example 6 of the '974 patent, the product was an amorphous solid.

16. The product of repeat experiment 12A represents an anomaly. The product was determined to be a crystalline substance by X-ray powder diffraction; however, the degree of crystallinity was not calculated. More importantly, the product was determined to have a methanol content of 22%. In my opinion, a methanol content of this magnitude could adversely diminish the degree of consistency and stability which is essential in the manufacture and storage of pharmaceutical substances. For example, owing to a high methanol content of 22%, a product like that of repeat experiment 12A would be unstable in a humid environment in which there is an increased likelihood that the methanol content would be at least partly, if not to a greater extent, exchanged and replaced by water. Moreover, the irregularity of repeat experiment 12A is made evident by the noncrystalline, amorphous structure that was consistently determined for each of the products of repeat experiments 12B and 12C, above, and sample B of the '342 application.

17. Based on my experience, the term "crystalline" is used differently by organic and analytical chemists to describe a compound. At the time of the invention of the '974 patent, the organic chemists at Hässle would perform a visual inspection of a solid reaction product and, together with certain other physical properties of the product, e.g., melting point, would then make a determination whether or not the product was "crystalline". This was the then standard and acceptable laboratory procedure at Hässle. In contrast, it is expected that an analytical chemist would employ some analytical means for determining whether or not a compound actually possesses a "crystalline" structure.

18. The protocol and reported results of Example 6 of the '974 patent were taken directly from the laboratory notebook of the organic chemists who conducted the research underlying the

invention of the '974 patent. Example 6 does not state that the crystallinity of the product was determined by an analytical method. Specifically, there is no suggestion in Example 6, or anywhere else in the specification of the '974 patent, of any procedure for determining either the presence of a crystalline structure or the degree of crystallinity of the omeprazole products of the '794 patent. Rather, the conclusion that the product of Example 6 was "crystalline" was based on a visual inspection of the precipitate and determination that the solid product had a narrow melting point range (178°-180°).

19. The weight of (a) the results of repeat experiments 12A-C, above, (b) the disclosure of 0% crystallinity of sample B in the specification of the '342 application and (c) the absence of a controlled crystallization step as part of the prior art process forces the conclusions that, although the product of Example 6 of the '974 patent was in a solid state, the product was amorphous, and the process and product of the claimed invention give a magnesium omeprazole salt product that is more suitable and, hence, preferred as a pharmaceutical substance for large scale manufacturing processes.

20. Furthermore, the degree of improved stability which distinguishes the claimed magnesium omeprazole salt is not suggested by Example 6 of the '974 patent or even when the '974 patent is taken in its entirety. With reference to Paragraph 13 and Table 1, above, the percentage area of the total elution profile occupied by the degradation products and contaminants of the claimed magnesium omeprazole salt, i.e., the ¶11 product, is essentially the same at zero time and after one month. Likewise, at the end of a three month exposure to open air at 40°C and 75% relative humidity, the ¶11 product did not show any significant deterioration. This compares favorably

with the results obtained with the ¶12B and ¶12C products. Specifically, the data shows that the claimed magnesium omeprazole salt, i.e., the ¶11 product, is 16 times more resistant at 50°C and 18 times more resistant at 40°C and75% relative humidity than the prior art represented by the ¶12B product after only one month exposure to open air. In my opinion, the degree of improved stability which is possible with the claimed invention, e.g., 16-18 times more stable, was not only unexpected but was unattainable prior to the discovery of the instant process for making a magnesium omeprazole salt having a degree of crystallinity greater than 70%.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or patent issuing thereon.

Dated: September 29, 1998

Per Lindberg

EXHIBIT 22

V.T.

Office Action Summary	Application No. 08/313,342	Applicant(s) Kallstrom et al.
	Examiner Jane Fan	Group Art Unit 1203

☒ Responsive to communication(s) filed on *Oct. 30,and Nov. 6 1997* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-4, 6-17, and 29-31* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-4, 6-17, and 29-31* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-2, 29-30 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim of prior U.S. Patent No. 5,690,960. This is a double patenting rejection.

Note the word "comprising" is an open-ended word.

Claims 1-2, 29-30 are directed to the same invention as that of claims of commonly assigned pat' 5,690,960. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

use 5693818 parent file

Claims 1-4, 6-17,29-31 are rejected under 35 U.S.C. 103(a) as being obvious over pat'4,738,974 and pat' 5,714,504 (patent date 2/3/98 SN 08/376,512).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application of any unclaimed subject matter prior to the effective U.S. filing date of the reference under 37 CFR 1.131.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-17, 29-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 4,738,974 and

5,714,504. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain overlapping subject matter.

Applicants' remarks (both filed on Dec. 11, 1996 and Oct. 30, 1997) and the affidavit have been carefully considered but are not convincing for the following reasons:

1. The showing of better stability for the salt is expected. Note col. 1, line 56 of pat 4,738,974. It is only when the greater stability would not have been expected that it may constitute a basis for patentability. If the beneficial results shown for a compound would have been expected, said results are evidence of obviousness, rather than unobviousness. In re Gershon, 54 CCPA 1066, 372 F.2d 535, 152 USPQ 602 (1967); In re Skoll, 523 F.2d 1392, 187 USPQ 481 (CCPA 1975); In re Hoffman, 556 F.2d 539, 194 USPQ 126 (CCPA 1977).

2. The data comparing neutral and magnesium salt of omeprazole are not releavant Magnesium salt of omeprazole prepared as in example 6 of the art should be compared with the Magnesium salt of omeprazole prepared in the instant application.

3. If applicants are impugning the method of prepaing crystalline solid of omeprazole magnesium salt in example 6 of pat' 4,738,974, they must do so with a preponderance of evidence, since a u. S. Patent is presumed valid.

Claim 5 was cancelled. If applicants wish this claim to be reinstated, applicants have to do it by amendment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANE FAN whose telephone number is (703) 308-4705.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JTF January 27, 1998

JANE FAN
PRIMARY EXAMINER
GROUP 1200

EXHIBIT 23

1612

1103326-0109

#16/5
8-9-98

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Källström et al.
Serial No.	: 08/313,342
Filed	: September 27, 1994
For	: A NOVEL COMPOUND FORM
Examiner	: J. Fan
Group Art Unit	: 1612

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents Washington, D.C. 20231.

John M. Genova — 32,224
Attorney Name — PTO Reg. No.

John M Genova — 31. July 1998
Signature — Date of Signature

Commissioner of Patents and Trademarks
Washington, D.C. 20231

AMENDMENT

Sir:

Applicants submit this Amendment in response to the Office Action, mailed February 3, 1998, and concurrently submit a petition for a three-month extension of time. Enclosed is a check in the amount of Nine Hundred and Fifty Dollars ($950.00) to cover the extension fee as required by 37 C.F.R. §§1.17(c) and 1.136(a).

08/04/1998 SLHOANG 00000098 08313342
01 FC:117 950.00 OP

E

IN THE CLAIMS:

Please amend the claims as follows:

Cancel claim 12.

Amend claims 7-9, 16 and 17 as follows:

E1

6. (Amended) The omeprazole magnesium salt according to claim 1 having a solvent content ~~containing~~ less than 0.1% by weight of solvent as determined by gas chromatography.

7. (Amended) The omeprazole magnesium salt according to claim 1 having a solvent content ~~containing~~ less than 0.05% by weight of solvent as determined by gas chromatography.

E2

9. (Twice amended) A process for the manufacture of magnesium omeprazole according to claim 1 comprising in consecutive steps

a) treating omeprazole or salt thereof with magnesium alcoholate in a solution,

b) separating inorganic salts from the reaction mixture,

c) crystallizing magnesium omeprazole by the addition of water, and

d) isolating the obtained crystalline magnesium omeprazole.

~~In~~ claim 16, line 2, delete "preferably".

In claim 17, line 1, delete "9" and insert therefor -- 31 --.

Add new claims 32-36:

32. The omeprazole magnesium salt of claim 6 or 7, wherein the solvent is an aqueous alcohol.

33. The omeprazole magnesium salt of claim 6 or 7, wherein the solvent is methanol.

34. The omeprazole magnesium salt according to claim 1 wherein the hygroscopicity is less than 2% increase of weight upon storage for one month at up to 94% relative atmospheric humidity as determined by gravimetry.

~~35. An improved form of a magnesium omeprazole salt, wherein the improvement comprises a degree of crystallinity of not less than 70% as determined by X-ray powder diffraction.~~

36. In a process for the manufacture of a crystalline magnesium salt comprising, (a) treating omeprazole or a salt thereof with magnesium alcoholate in a solution, (b) crystallizing magnesium omeprazole and (c) isolating the obtained crystalline magnesium omeprazole, wherein the improved process comprises separating inorganic salts from the reaction mixture prior to the crystallization step by the addition of water.

REMARKS

I. Description of Amended Claims

Claims 7 and 8 have been amended to better describe the invention. Claim 9 has been amended by the insertion of the embodiment recited by claim 12, now canceled. Support for new claims 32 and 33 is found on page 5, lines 15-18, of the specification as originally filed. New claim 34 represents original claim 5 that was inadvertently canceled in a previous amendment. New claims 35 and 36 correspond to original claims 1 and 9, respectively, which have been written in Jepson form to clearly recite the improvement vis-à-vis the prior art. Applicants submit that no new matter has been added by any of the amendments or new claims

II. Rejection Under 35 U.S.C. §101 and Priority Issues

Claims 1-2 and 29-30 are rejected under 35 U.S.C. §101 as claiming the same invention as that of U.S. Patent No. 5,690,960 (the "'960 patent"). The Examiner has also required that the issue of priority under 35 U.S.C. §102(g) and possibly under 35U.S.C. §102(f) be resolved with regard to claims 1-2 and 29-30 of the present application and the '960 patent.

The subject application and the '960 patent have identical foreign priority dates (9. July 1993); identical PCT filing dates (8. July 1994); and identical §371 and §102(e) dates (27. September 1994). Therefore, Applicants submit that the rejection of claims 1-2 and 29-30 under 35 U.S.C. §101 is improper and request withdrawal thereof. Moreover, in view of the filing dates, there is no issue of priority.

III. Rejections Under 35 U.S.C. §103 and Obviousness-Type Double Patenting

A. U.S. Patent No. 5,714,504 As Prior Art

Claims 1-4, 6-17, and 29-31 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5.714,504 (the "'504 patent"). The same claims are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatenable over the claims of the '504 patent.

The claims of the subject application are directed to the racemic mixture of a magnesium omeprazole salt having a degree of crystallinity which is greater than 70% as determined by X-ray powder diffraction. The priority date of the subject application is 9. July 1993 (PCT filing date = 8. July 1994; U.S. Filing Date = 27. September 1994).

The cited '504 patent is a continuation-in-part ("CIP") application having a U.S. effective filing date of 23. January 1995. The parent of the '504 patent is U.S. Patent Application Serial No. 08/256,174, now U.S. Patent No. 5,693,818 (the "'818 patent") (priority date = 28. May 1993; PCT filing date = 27. May 1994; U.S. filing date = 28. June 1994). The '818 patent is directed to a process for the preparation of the (+)- and (-)-enantiomers of omeprazole. Some of the Examples of the '818 patent describe the preparation of the magnesium salts of the (+) and (-)-enantiomers of omeprazole. However, there is no suggestion in the '818 patent of either a magnesium omeprazole salt having a degree of crystallinity greater than 70% nor is there a suggestion of any process for making a magnesium omeprazole salt having a degree of crystallinity greater than 70%.

Examples 6 and 7 of the CIP '504 patent discloses the magnesium salt of the (+)- and (-)-enantiomer of omeprazole in crystalline form. However, there is no suggestion that degree of crystallinity of the enantiomers is or should be greater than 70%. In the '504 patent, Applicants

successfully demonstrated patentability by showing that the (-)-enantiomer of omeprazole unexpectedly exhibits a different and more advantageous pharmacokinetic profile than either the racemic mixture or the (+)-enantiomer of omeprazole (See, Declaration of Andersson). The U.S. effective filing date for the new matter that was added to the CIP is 23. January 1995, which is subsequent to the priority date (9. July 1993) of the subject application. Therefore, Applicants submit that the '504 patent is not proper prior art relative to the subject matter of the claimed invention.

For all of the foregoing reasons, the rejection of claims 1-4,6-7 and 29-31 on the basis of the '504 patent is improper. Withdrawal is requested of the rejection under 35 U.S.C. §103(a) and the obviousness-type double patenting rejection.

B. U.S. Patent No. 4,738,974 As Prior Art

Claims 1-4, 6-17, and 29-31 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 4,738,974 (the "'974 patent"). The same claims are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatenable over the claims of the '974 patent.

On page 2 of the specification, it is stated that the crystallization of magnesium omeprazole salts is critical to the preparation of a product that is suitable as a pharmaceutical substance. Advantageously, Applicants have discovered a crystallization process for making a novel form of a magnesium omeprazole salt having a degree of crystallinity of not less than 70% as determined by X-ray powder diffraction. It is also Applicants' discovery that this degree of crystallinity is essential to the full scale manufacturing of pharmaceutical formulations comprising a magnesium omeprazole salt.

As previously argued in the Amendment and Response submitted on 27. October 1997, the '974 patent is silent with regard to the criticality of the degree of crystallinity to the full scale manufacturing of a magnesium omeprazole salt for pharmaceutical formulations. The '974 patent fails to provide any guidance regarding methods for determining crystallinity. Finally, the '974 patent does not suggest the claimed method for making and obtaining a novel omeprazole salt that is characterized by a degree of crystallinity greater than 70% as measured by X-ray powder diffraction. For all of these reasons, Applicants submit that the claimed invention is patentable over the '974 patent.

In the paragraphs identified "1." And "2." on page 4 of the Office Action, the Examiner provides a discussion regarding data that would support the patentability of the claimed invention when compared to the '974 patent. As suggested by the Examiner, Applicants have completed repeat experiments of Example 6 of the '794 patent and are in the process of conducting stability testing over a three month period with regard to those products. Shortly after the conclusion of that three month period, the data comparing the results with the magnesium omeprazole salts of the claimed invention will be set forth in a Declaration and submitted to the Examiner in due course. The delay, if any, in filing the Declaration is due to the practical fact it has required time to prepare the products of the repeat experiments and conduct stability testing over a three month period. Therefore, the undersigned attorney requests the courtesy of a telephone call from the Examiner if the Declaration has not been received by the Patent Office at such time when the application is again examined by the Examiner.

However, with specific regard to the obviousness-type double patenting rejection, Applicants respectfully submit that the rejection is improper. The inquiry is whether the claimed invention of the subject application is obvious when compared with the subject matter of the

claims of the '974 patent. The specification of the '974 patent may not be used as prior art for the purpose of supporting an obviousness-type double patenting rejection. Therefore, when only the claims of the cited reference are compared with the claims of the application, it is abundantly clear that none of the claims of the '974 patent either expressly recites or even remotely suggests a crystalline form of a magnesium omeprazole salt. Consequently, for even stronger reasons, none of the claims of the '974 patent either expressly recites or even remotely suggests a crystalline form of a magnesium omeprazole salt having a degree of crystallinity greater than 70%.

By themselves, the claims of the '974 patent are resoundingly silent on the desirability, suggestibility and advantages of an omeprazole magnesium salt having a degree of crystallinity greater than 70%. The claims do not even mention the word "crystallinity". Accordingly, Applicants respectfully submit that the double-patenting rejection is improper and withdrawal thereof is requested.

CONCLUSION

The Amendment and Remarks are fully responsive to the outstanding Office Action. In view of the preceding Remarks, Applicants request removal of the rejections based on U.S. Patent Nos. 5,690,960 and 5,714,504. Furthermore, Applicants have demonstrated that the obviousness-type double patenting rejection based on U.S. Patent No. 4,738,974 is improper since the claims of that patent do not suggest a crystalline magnesium omeprazole salt having a degree of crystallinity greater than 70%. Withdrawal of the obviousness-type double patenting rejection is requested.

As stated Section III(B), above, Applicants will submit data in declaration form supporting the arguments of record regarding the patentability of the claimed invention over U.S. Patent No. 4,738,974.

Any additional fees due in connection with this response should be charged to Deposit Account No. 23-1703.

Dated: July 31, 1998

Respectfully submitted,

John M. Genova
Reg. No. 32,224
Attorney for Applicants

White and Case LLP
Patent Department
1155 Avenue of the Americas
New York, NY 10036-2787
(212) 819-8200

EXHIBIT 24

~~CLAIMS~~ WHAT IS CLAIMED IS:

1. Magnesium ~~omeprazole~~ characterized in having a degree of crystallinity which is higher than 70% as determined by X-ray powder diffraction.

2. ~~Magnesium omeprazole~~ according to claim 1 wherein the degree of crystallinity is higher than 75%.

3. ~~Magnesium omeprazole~~ according to claim 1 wherein the mean particle diameter as determined by laser diffraction technique is less than 30μm, and preferably less than 20μm.

4. ~~Magnesium omeprazole~~ according to claim 1 wherein the density is between 1.33 g/cm^3 and 1.35 g/cm^3 as determined by powder pycnometer.

5. ~~Magnesium omeprazole~~ according to claim 1 wherein the hygroscopicity is less than 2% increase of weight upon storage for one month at up to 94% relative atmospheric humidity as determined by gravimetry.

6. ~~Magnesium omeprazole~~ according to claim 1 wherein the water content is between 5% and 10% by weight as determined by titration according to Karl Fischer.

7. ~~Magnesium omeprazole~~ according to claim 1 containing less than 0.1% by weight of solvent as determined by gas chromatography.

8. ~~Magnesium omeprazole~~ according to claim 1 containing less than 0.05% by weight of solvent as determined by gas chromatography.

9. A process for the manufacture of magnesium omeprazole according to any of claims 1 to 8 characterized by in consecutive steps

a) treating omeprazole or a salt thereof with magnesium alcoholate in a solution,

b) separating inorganic salts from the reaction mixture,

c) crystallizing magnesium omeprazole,

d) isolating the obtained crystalline magnesium omeprazole and, optionally,

e) purifying and drying the crystalline magnesium omeprazole using conventional methods.

10. A process according to Claim 9 wherein the magnesium alcoholate is magnesium methyl alcoholate.

11. A process according to claim 9 wherein the solvent is methanol.

12. A process according to claim 9 ~~wherein the~~ crystallization is accomplished by addition of water.

13. A process according to claim 9 wherein the isolation of the magnesium omeprazole is performed by centrifugal separation of the crystals.

14. A process according to claim 9 wherein the isolation of the magnesium omeprazole is performed by crystallization followed by filtration of the crystals.

15. A process according to ~~claim 9~~ claim 31 wherein the purification of the magnesium omeprazole crystals is performed by washing the crystals with a solution of polar solvents.

16. A process according to ~~claim 9~~ claim 31 wherein the magnesium omeprazole crystals are dried ~~preferably~~ under reduced pressure.

17. A process according to claim 9 wherein the drying of the magnesium omeprazole crystals is performed by evaporating the remaining solvent by heating.

18. Magnesium omeprazole obtained by a process according to any of claims 9 to 17.

19. A pharmaceutical composition containing magnesium omeprazole according to any of claims 1 to 8 as an active ingredient.

20. A pharmaceutical formulation for oral administration containing magnesium omeprazole according to any of claims 1 to 8 as an active ingredient.

21. A tablet formulation containing magnesium omeprazole according to any of claims 1 to 8 as an active ingredient.

22. Magnesium omeprazole according to any of claims 1 to 8 for use in therapy.

23. Magnesium omeprazole according to any of claims 1 to 8 for use in inhibiting gastric acid secretion in mammals and man.

24. Magnesium omeprazole according to any of claims 1 to 8 for use as an agent with gastric mucosa protective activity in mammals and man.

25. Magnesium omeprazole according to any of claims 1 to 8 for use in the treatment of gastric acid related diseases in mammals and man.

26. The use of magnesium omeprazole according to any of claims 1 to 8 in the manufacture of a medicament for inhibiting gastric acid secretion.

27. The use of magnesium omeprazole according to any of claims 1 to 8 in the manufacture of a medicament for obtaining gastric mucosa protective activity.

28. ~~The use of~~ magnesium omeprazole according to any of claims 1 to 8 in the manufacture of a medicament for the treatment of gastric acid ~~related~~ diseases.

~~29~~ 21. A method for inhibiting gastric acid secretion in mammals and man ~~by~~ comprising administering to a host in need thereof a therapeutically effective dose of magnesium omeprazole according to any of claims 1 to ~~8~~ 4, 6-8 and ~~34~~ 10.

~~30~~ 22. A method for the treatment of gastric acid related diseases in mammals and man ~~by~~ comprising administering to a host in need thereof a therapeutically effective dose of magnesium omeprazole according to any of claims 1 to ~~8~~ 4, 6-8 and ~~34~~ 10.

add EB

add EB

EXHIBIT 25

Errol B. Taylor (ET 6742)
John M. Griem, Jr. (JG 2609)
Claire A. Gilmartin (CG 0066)
MILBANK, TWEED, HADLEY &
McCLOY LLP
1 Chase Manhattan Plaza
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(212) 530-5000

Attorneys for Plaintiffs
and Counterclaim-Defendants
AstraZeneca AB, Aktiebolaget Hässle,
AstraZeneca LP, KBI Inc. and KBI-E Inc.

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE and ASTRAZENECA LP, KBI INC. and KBI-E INC., Plaintiffs and Counterclaim-Defendants, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC. Defendants and Counterclaim-Plaintiffs.	07-CV-6790 (CM)(FM)

PLAINTIFF ASTRAZENECA'S FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS ON THE MERITS (NOS. 1-6)

Plaintiffs, AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively "AstraZeneca"), in accordance with Rule 34 of the

Federal Rules of Civil Procedure, request that Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL") provide written responses and the appropriate documents and things responsive to these Requests and produce same for inspection and copying by AstraZeneca, within thirty days of service, at the Office of Milbank, Tweed, Hadley & McCloy LLP, 1 Chase Manhattan Plaza, New York, NY 10005-1413.

REQUESTS

DOCUMENT REQUEST NO. 1

The Chemistry, Manufacturing, and Controls ("CMC") section of DRL's ANDA No. 78-878, including all related supplements and amendments.

DOCUMENT REQUEST NO. 2

Portions of the Drug Master Files referred to in DRL's ANDA No. 78-878, including all supplements and amendments, relating to properties of DRL's omeprazole magnesium, including, crystallinity, particle size, hygroscopicity, water content, methanol content and density.

DOCUMENT REQUEST NO. 3

Documents reflecting the results and procedures used in all testing performed by or on behalf of DRL regarding the degree of crystallinity of the omeprazole magnesium in each batch of DRL's omeprazole magnesium, including the batch of API sample DRL produced to AstraZeneca, as determined by x-ray powder diffraction of a micronized sample of the omeprazole magnesium.

DOCUMENT REQUEST NO. 4

Documents reflecting the results and procedures of all water content testing performed by or on behalf of DRL on each batch of DRL's omeprazole magnesium and the product made according to DRL's ANDA 78-878.

DOCUMENT REQUEST NO. 5

240 capsules (8 plastic bottles containing 30 capsules each) of DRL ANDA Product and any package inserts or instructions to be included with the product when sold of each of the following batches: MG002A04 (also denoted OMG00604); MG003A04 (also denoted OMG00704); MG004B04 (also denoted OMG00804); MG018G05 (also denoted OMG01305); MG019G05 (also denoted OMG01405); MG020G05 (also denoted OMG01505); MG021G05 (also denoted OMG01605); MG030L05 (also denoted OMG02405); MG001A06 (also denoted OMG00106); MG002B06 (also denoted OMG00206); EC6319.

DOCUMENT REQUEST NO. 6

In-process samples from each batch of DRL ANDA Product listed in Document Request 5 at the stage after drying, before micronization in step 6.3, stage 1 (Exhibit 13, DRLOMEMG00155) and at the stage when the omeprazole magnesium is loaded into the mixture used to spray coat the sugar spheres in step 2.1.7 (Exhibit 14, DRLOMEMG00058).

Date: November 19, 2007

By: _____
Errol B. Taylor (ET 6742)
John M. Griem, Jr. (JG 2609)
Claire A. Gilmartin (CG 0066)

MILBANK, TWEED, HADLEY &
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AKTIEBOLAGET HÄSSLE,
ASTRAZENECA LP, KBI INC.
AND KBI-E INC.

EXHIBIT 26

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May 6, 2008

VIA FACSIMILE & FEDERAL EXPRESS
Errol B. Taylor, Esq.
Milbank, Tweed, Hadley & McCloy LLP
1 Chase Manhattan Plaza
New York, N.Y. 10005-1410

Re: AstraZeneca, et al. v. Dr. Reddy's Laboratories, et al.
Case No. 07-Civ.-6790

Dear Errol:

We are gathering the documents called for in Par. (3) of Judge McMahon's "Ruling on Astra-Zeneca's Request for Infringement Discovery."

Please confirm that you and any persons receiving these documents will observe the same restrictions that were placed on the confidential DRL documents and information that we have already produced (See letters dated October 16 and 17, 2007). In particular: DRL's confidential information and information derived therefrom will be used only to determine whether DRL infringes the two patents-in-suit; the persons's receiving DRL's confidential information and information derived therefrom will continue to not be involved in patent prosecution; and, DRL's confidential information and information derived therefrom will only be disclosed to the following individuals:

1. Milbank, Tweed, Hadley & McCloy LLP, outside counsel for AstraZeneca;
2. Jeffrey Pott, Assistant General Counsel for AstraZeneca Pharmaceuticals LP;
3. Marcus Heifetz, Senior Counsel for AstraZeneca Pharmaceuticals LP;
4. Katarina Ageborg, Assistant General Counsel for AstraZeneca;
5. Kurt Lövgren, Ph.D., AstraZeneca employee, Scientific Advisor;
6. Ingvar Ymén, Ph.D., AstraZeneca employee, Principal Scientist;
7. Frans Langkilde, AstraZeneca Scientist;
8. Karin Lovquist, AstraZeneca Scientist;
9. Joacim Gustafsson, AstraZeneca Scientist;
10. Dr. Shen Luk and Dr. Martyn Davies of Molecular Profiles, and perhaps, one or two other Molecular Profile scientists to be identified; and,
11. William Krovatin.

Sincerely,

Louis H. Weinstein

LHW/mit 676523

EXHIBIT 27

MILBANK, TWEED, HADLEY & McCLOY LLP

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May 7, 2008

VIA FACSIMILE (973-379-7734)
Louis H. Weinstein
Budd Larner
150 John F. Kennedy Parkway
Short Hills, NJ 07078-2703

Re: *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*
07-civ-6790 (CM)(FM)

Dear Louis:

We write in response to your May 6, 2008 letter.

AstraZeneca looks forward to receiving accurate and complete copies of DRL's ANDA and DMF documents called for in Par. (3) of Judge McMahon's "Rulings on AstraZeneca's Request for Infringement Discovery." Also, please advise AstraZeneca of a date earlier than May 23, 2008 when AstraZeneca can take a deposition at Milbank's offices in New York, NY of a person with knowledge of DRL's manufacturing process called for in Par. (9) of the Discovery Ruling. Please provide the documents and deposition date before the close of business on Friday, May 9, 2008.

To manage the handling of confidential information, AstraZeneca proposes that the parties enter into a protective order, a copy of which is attached. The terms of the proposed order are the same as the protective order that will apply to information in the Nexium litigation between the parties currently pending in the District of New Jersey, Civil Action No. 08-328 (JAP). Please advise if DRL will agree to the proposed protective order.

Very truly yours,

John M. Griem, Jr.

Enclosures: Proposed protective order

cc: Michael Imbacuan, Esq.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE and ASTRAZENECA LP, KBI INC. and KBI-E INC.,	Civil Action No. 07-6790(CM)(FM)
Plaintiffs and Counterclaim-Defendants	Judge Colleen McMahon
v.	
DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,	STIPULATED PROTECTIVE ORDER ON CONFIDENTIALITY
Defendants and Counterclaim-Plaintiffs	

Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively "AstraZeneca") and defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL"), by and through their undersigned counsel, hereby stipulate and agree that, in order to facilitate coordinated or consolidated discovery, the following protective order ("Order" or "Protective Order") shall govern the use and handling of materials containing trade secrets and other confidential research, development and commercial information in the above captioned case, and request that the Court enter this stipulated Order in the above captioned case.

IT IS HEREBY AGREED AND ORDERED:

1. Designation Of Protected Material

a. Any person or entity (the "Producing Party") producing documents, things, information or other materials in the above captioned cases ("Produced Material")

for inspection or review by another person or entity (the "Receiving Party") may designate as "Confidential" or "Attorney Confidential" pursuant to this Order any Produced Material that the Producing Party in good faith considers to be, reflect or reveal a trade secret or other confidential research, development or commercial information in accordance with Fed. R. Civ. P. 26(c)(7), or other information required by law or agreement to be kept confidential.

b. The Attorney Confidential designation shall be limited to material which contains or comprises sensitive financial, marketing, customer, clinical, regulatory, research, development, scientific or commercial information, and which would likely prejudice or cause the Producing Party harm if disclosed to the technical employees of the Receiving Party.

c. All information designated as Confidential or Attorney Confidential, including all copies, excerpts and summaries thereof, and all information contained therein or derived therefrom shall hereinafter be referred to as "Protected Material." Notwithstanding such designation, Protected Material does not include information that:

(1) Was, is, or becomes public knowledge, not in violation of this Protective Order;

(2) Is acquired or was possessed by the Receiving Party in good faith without confidentiality restrictions or from a third party not subject to this Protective Order;

(3) Is discovered independently by the Receiving Party by means that do not constitute a violation of this Protective Order; or

(4) Was, is, or becomes expressly released from being designated as Protected Material by the Producing Party or by order of the Court.

2. Labeling Of Protected Material

a. The designation of Protected Material for purposes of this Order shall be made in the following manner:

(1) With regard to written material (including transcripts of depositions or other testimony) and electronic images (such as TIFFs), a legend shall be affixed to each page substantially in the form, "Confidential" or "Attorney Confidential;" and

(2) With regard to non-written material, such as recordings, magnetic media, photographs and things, a legend substantially in the above form shall be affixed to the material in any suitable manner.

b. Materials described in Paragraphs 2.a(1) and 2.a(2) made available by a Producing Party for inspection without confidentiality legends shall be deemed to be Attorney Confidential until otherwise designated by the Producing Party.

c. Each transcript of any deposition shall be treated as Attorney Confidential in its entirety, and the court reporter shall affix such a designation to the cover and every page of the transcript. Testimony about Protected Material of a Producing Party shall be deemed Protected Material disclosed by the Producing Party pursuant to this Protective Order. Within twenty (20) days after the deposition, any party may propose Confidential or Non-Confidential designations by notifying all parties, in writing, of specific pages and lines of the transcript to be either Confidential or Non-Confidential. The Confidential or Non-Confidential designations shall not take effect until all parties agree to such designations. In the event of different designations for the same text, the parties will confer to reach agreement on the appropriate designation, as set forth in Paragraph 1 hereof, and may seek Court intervention if necessary to resolve any disagreement. Until

the issue is resolved, the transcript portions at issue shall be treated as the most restrictive designation made by anyone.

3. Disclosure And Use Of Protected Material Absent an agreement of the Producing Party or an Order to the contrary by this Court or other court of competent jurisdiction, a Receiving Party shall use Protected Material solely for purposes of litigating the above captioned cases and not for any other purpose, including, without limitation, any business or commercial purpose. If a Receiving Party is served with a subpoena, discovery request in an action other than one of the above captioned cases, or any other request seeking by legal process the production of Protected Material, such Receiving Party shall promptly notify the Producing Party, and inform the persons seeking discovery in writing (with copy to the Producing Party and the Court) that providing the Protected Material would be a violation of this Protective Order.

4. Qualified Persons A Receiving Party shall disclose Protected Material only to the following Qualified Persons, their clerical, support and secretarial staffs, paralegals and assistants. All rights, obligations and restrictions in this Protective Order shall apply to such Qualified Persons as if they were the Receiving Party. All in-house attorneys who are assisting in litigating the above-captioned cases are prohibited from being directly involved with prosecution of patents relating to omeprazole for a period of one year following the conclusion of the above cases, including all appeals.

a. U.S. outside counsel of record in the above captioned cases, and other attorneys working at their respective law firms (collectively, "Outside Counsel").

b. For AstraZeneca:

(1) The following are Qualified Persons for all Protected Material (*i.e.*, Confidential and Attorney Confidential):

Katarina Ageborg

Marcus Heifetz
William Krovatin
Jeffrey Pott
Joacim Gustaffson
Frans W. Langkilde
Karin Lovquist
Ingvar Ymen

(2) The following are Qualified Persons only for Protected Material designated as Confidential (*i.e.*, not Attorney Confidential):

Kurt Lövgren

c. For DRL:

(1) The following are Qualified Persons for all Protected Material (*i.e.*, Confidential and Attorney Confidential):

[insert]

(2) The following are Qualified Persons only for Protected Material designated as Confidential (*i.e.*, not Attorney Confidential):

[insert]

d. Experts and third-party technical service contractors who are not present employees of any party to the above captioned cases, who are requested by Outside Counsel of the Receiving Party to furnish technical or expert services in connection with this litigation.

e. Third-party contractors involved solely in providing litigation support services to Outside Counsel.

f. The Court and its personnel.

g. An officer or other person before whom a deposition is taken in the above captioned cases, including any stenographic reporter or videographer.

h. Any other person agreed to by the parties to the above captioned cases or allowed by the Court.

5. Restrictions Not Imposed By This Order

a. This Order shall not restrict any Producing Party's use, for any purpose, of its own Protected Material.

b. This Order shall not restrict any counsel who is a Qualified Person from rendering advice to the party it represents in the above captioned cases, and in the course thereof, from generally relying upon his or her examination of Protected Material. In rendering such advice, the attorney shall not disclose directly or indirectly the specific content of any Protected Material where such disclosure would not otherwise be permitted under the terms of this Order.

6. Notice And Acknowledgement Of Order

a. Every Qualified Person to whom Protected Material or information contained therein is to be disclosed, summarized, described, characterized, or otherwise communicated or made available in whole or in part, first shall be advised that the material or information is being disclosed pursuant and subject to the terms of this Order.

b. Before any disclosure of Protected Material is made to a Qualified Person pursuant to Paragraphs 4.b-4.c or 4.h, Outside Counsel for the Receiving Party shall: (a) provide the Qualified Person with a copy of this Protective Order; (b) explain its terms; and (c) obtain the Qualified Person's written agreement, in the form of Exhibit A hereto, to comply with and be bound by its terms. All Qualified Persons to whom disclosure of Protected Material is intended shall confirm their understanding and agreement to abide by the terms of this Order by signing a copy of the acknowledgement attached as Exhibit A.

7. Notification Of Intent To Disclose And Objections

a. Before Protected Material is disclosed to a Qualified Person under Paragraphs 4.b-d or 4.h, the Receiving Party shall, at least ten (10) business days prior to such disclosure, notify the Producing Party in writing, of its intent to disclose Protected Material. Such notification shall include the name, current address, and employment affiliation (including job title, if any) of the Qualified Person to whom such disclosure is proposed. The notification shall also include a copy of the signed acknowledgement made in conformance with Paragraph 6 of this Order. With respect to Qualified Persons listed in Paragraph 4.d, the notification shall further include a current resume or curriculum vitae from the person.

b. The notification and signed acknowledgement shall be delivered by hand or by facsimile with confirmation by overnight courier.

Notification to AstraZeneca shall be delivered to:

Errol Taylor
Milbank, Tweed, Hadley & McCloy LLP
1 Chase Manhattan Plaza
New York, NY 10005
Facsimile: (212) 822-5432

Notification to DRL shall be delivered to:

Louis H. Weinstein
Budd Larner
150 John F. Kennedy Parkway
Short Hills, NJ 07078-2703
Facsimile: (973) 379-7734

c. If a Producing Party receiving a notification of intent to disclose Protected Material believes in good faith that such disclosure of Protected Material would be injurious or prejudicial, it may object to the proposed disclosure by giving written notice of such objection to the Receiving Party seeking to make the disclosure. Such notice

shall include the basis for the objection and shall be delivered in accordance with Paragraph 7.a within ten (10) business days of receipt of the notification of intent to disclose to which objection is made. If the Producing Party objects, the proposed disclosure shall not take place until the objection is resolved by agreement of the Producing Party or order of this Court. Failure to object within the time period set forth above shall be deemed a consent. If the objection cannot be resolved, either party may seek relief from the Court but the Producing Party shall have the burden of proof that the intended disclosure should not occur.

d. Any party may seek to substitute another in-house attorney for an attorney listed in Paragraphs 4.b-c by following the procedures described in this paragraph, sections 7.a-c. Any party may seek to add in-house non-attorney scientific advisors to the list of individuals permitted access under paragraphs 4.b(1) or 4.c(1) by notifying the parties that the individual will have access to all Protected Material and by following the procedures identified in this paragraph, sections 7.a-c. Any party may seek to add in-house non-attorney scientific advisors to the list of individuals permitted access under paragraphs 4.b(2) or 4.c(2) by notifying the parties that the individual will have access only to Protected Material designated as Confidential and by following the procedures identified in this paragraph, sections 7.a-c.

8. Examination Of Witnesses at Deposition Protected Material may be disclosed to a witness at a deposition (a) if the witness is an officer, director, or employee of the party who produced such Protected Material or (b) if the witness was formerly an officer, director, or employee of the party who produced such Protected Material, and the Protected Material existed during the period of his or her service or employment.

9. Inadvertent Production Of Privileged Or Protected Material

a. If information subject to a claim of attorney-client privilege, attorney work product immunity or any other legal privilege protecting information from discovery is inadvertently produced, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege, work product immunity or other ground for withholding production to which the Producing Party or other person otherwise would be entitled, provided that the Producing Party identifies in writing that the inadvertently produced material is subject to a claim of immunity or privilege within ten (10) calendar days of discovery of the inadvertent production or within ten (10) calendar days of receiving notice from another party of potential inadvertent production. Upon a written claim of inadvertent production, the Receiving Party having custody of the inadvertently produced material shall return to the Producing Party that material and all copies or reproductions thereof of which that Receiving Party is aware in whatever form these materials exist, and that information may not be used for any purpose. The Receiving Party may subsequently move the Court for an Order compelling production of the material, but such motion shall not disclose the substance of the inadvertently produced material except to the extent that an *in camera* inspection of the materials may be requested.

b. Inadvertent failure to designate any material which a Producing Party claims should be Protected Material will not be deemed a waiver of the right to make that designation. Upon receiving notice of such failure to designate, all Receiving Parties shall cooperate to restore the confidentiality of the inadvertently or unintentionally disclosed Produced Material. No party shall be held in breach of this Order if, prior to notification of such later designation, such Produced Material had been disclosed or used in a manner inconsistent with such later designation. The Producing Party shall provide substitute copies bearing the corrected designation. The Receiving Parties shall return or certify the destruction of the undesignated Produced Material.

10. Obligations of Outside Counsel It shall be the responsibility of Outside Counsel to ensure strict compliance with the provisions of this Protective Order and to take reasonable and proper steps to ensure that all provisions thereof are made known to any person who shall examine Protected Material.

11. Pleadings All papers, documents and transcripts containing or revealing the substance of Protected Material shall be filed in accordance with and following a formal motion pursuant to Local Civil Rule 5.3(c) and placed in sealed envelopes bearing the caption of the case and marked:

CONFIDENTIAL
SUBJECT TO PROTECTIVE ORDER IN
CIVIL ACTION NO. 07-civ-6790(CM)(FM)
NOT TO BE OPENED EXCEPT BY ORDER OF THE COURT
OR CONSENT OF THE PARTIES

or similar markings as may be required by the Court.

12. Conclusion of the Action Within sixty (60) days after entry of a final judgment or dismissal with prejudice (including appeals or petitions for review) or the execution of a settlement agreement, finally disposing of all issues raised in one or more of the above captioned

cases, all Receiving Parties no longer in such case(s) shall: (a) return all Protected Material and any copies thereof to the appropriate Outside Counsel who produced the Protected Material; or (b) destroy such Protected Material. Each Receiving Party shall give written notice of such destruction to Outside Counsel for the Producing Party. However, Outside Counsel who are trial counsel may retain one copy of all pleadings for archival purposes. Further, all notes, summaries, or other documents prepared by Qualified Persons under Paragraphs 4.b-4.d and 4.h, derived from or containing Protected Material, shall after the conclusion of the action, be kept within the files of Outside Counsel who are trial counsel for the Receiving Party creating such work product, or be destroyed.

13. Contested Designations A Receiving Party shall not be obligated to challenge the propriety of a Producing Party's designations of any Protected Material at the time such designation is made, and failure to do so shall not preclude a subsequent challenge thereto. If the Receiving Party disagrees with the designation of any Protected Material, the Receiving Party may, after holding a meeting with the Producing Party, make a request of the Court for an order removing such Protected Material from the restrictions of this Protective Order.

14. Non-Waiver The production of Produced Material under the terms of this Order in response to a request by an opposing party shall not be construed to mean that the Producing Party has waived any objection to the production, relevancy or admissibility of said Produced Material. Nothing contained herein shall preclude any party from opposing any discovery on any basis. Further, nothing in this Order constitutes an admission by any party that any specific item of Protected Material is a trade secret or otherwise confidential and proprietary to a party.

15. Additional Parties If an additional party joins or is joined in the above captioned cases, the newly joined party shall not have access to Protected Material until all parties to the

above captioned cases agree to a supplemental Protective Order governing the protection of Protected Material.

16. Third Parties Any third party from whom discovery is sought in the above captioned cases may, in accordance with this Order, designate some or all of its production as Protected Material, and each Receiving Party will have the same rights, obligations and restrictions which that Receiving Party has with respect to the Protected Material of any other Producing Party.

17. Attendance At Proceedings If a deposition concerns Protected Material, the Producing Party shall have the right to exclude from the portion of the deposition concerning such information any person not authorized in accordance with Paragraph 4 hereof to have access to such material. All persons not authorized in accordance with Paragraph 4 hereof for access to Protected Material may be excluded from the trial and any hearings and conferences in these actions.

18. Unauthorized Disclosure In the event of disclosure of any Protected Material to a person not authorized to have access to such material, the party responsible for having made, and any party with knowledge of, such disclosure shall immediately inform Outside Counsel for the party whose Protected Material has thus been disclosed of all known relevant information concerning the nature and circumstances of the disclosure. The responsible party shall also promptly take all reasonable measures to ensure that no further or greater unauthorized disclosure or use of such information or materials is made. Each party shall cooperate in good faith in that effort.

19. Termination Of Access

a. In the event that any person or party ceases to be engaged in the conduct of these actions, such person's or party's access to Protected Material shall be terminated,

and all copies thereof shall be returned or destroyed in accordance with the terms of Paragraph 12 hereof, except that such return or destruction shall take place as soon as practicable after such person or party ceases to be engaged in the conduct of these actions.

b. The provisions of this Order shall remain in full force and effect as to any person or party who previously had access to Protected Material, except as may be specifically ordered by the Court or consented to by the Producing Party.

20. Production Prior To This Order Documents or things produced in these actions prior to entry of this Order and subject to confidentiality restrictions shall be redesignated by each Producing Party within 30 days of the entry of this Order in accordance with paragraph 2 hereof, to the extent not already appropriately designated "Confidential" or "Attorney Confidential." Until such time as the documents and things are redesignated (pursuant to this paragraph or otherwise), all documents or things produced prior to the date of this Order will be deemed "Attorney Confidential" under the terms of this Order.

21. Modification Stipulations may be made, between Counsel for the respective parties, as to the application of this Order to specific situations, provided that such stipulations are recorded in writing or contained in the record of any oral proceeding. Nothing contained herein shall preclude any party from seeking an order of the Court modifying or supplementing this Order.

Dated: _____

By: _____
Errol B. Taylor
John M. Griem, Jr.
Claire A. Gilmartin
MILBANK, TWEED, HADLEY & McCLOY LLP
1 Chase Manhattan Plaza
New York, New York 10005-1413
Telephone: (212) 530-5000
Facsimile: (212) 822-5432

Attorneys for Plaintiffs and Counterclaim-Defendants,
AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc., and KBI-E Inc.

Dated: _____

By: _____
Louis H. Weinstein
Michael Imbacuan
BUDD LARNER
150 John F. Kennedy Parkway
Short Hills, NJ 07078-2703
Telephone: (973) 379-4800
Facsimile: (973) 379-7734

Attorneys for Defendants and Counterclaim-Plaintiffs,
Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.

SO ORDERED:

Dated: _____

_____
Honorable Colleen McMahon
United States Judge

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE and ASTRAZENECA LP, KBI INC. and KBI-E INC.,	Civil Action No. 07-6790 (CM)(FM)
Plaintiffs and Counterclaim-Defendants	Judge Colleen McMahon
v.	
REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,	ACKNOWLEDGEMENT TO ABIDE BY THE PROTECTIVE ORDER
Defendants and Counterclaim-Plaintiffs	

I, _____, declare that:

1. I have read the foregoing Protective Order entered as an Order of the United States District Court for the Southern District of New York, in the action entitled *AstraZeneca AB et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civil Action No. 07-6790 (CM)(FM).

2. I understand and agree to be bound by the terms of this Protective Order.

3. I will hold in confidence and will not disclose to anyone who is not a Qualified Person under the Protective Order and will use only for purposes of these actions, any Protected Material disclosed to me.

4. I will return all Protected Material that comes into my possession, and documents or things that I have prepared relating thereto, to counsel for the party by whom I am employed or retained when requested to do so by that counsel.

5. I hereby submit to the jurisdiction of this Court for the purpose of enforcement of this Protective Order.

(Signature)

(Printed Name)

(Date)

EXHIBIT 28

BUDD LARNER
A PROFESSIONAL CORPORATION
COUNSELLORS AT LAW

150 JOHN F. KENNEDY PARKWAY
SHORT HILLS, NJ 07078-2703
973.379.4800
FAX 973.379.7734
www.buddlarner.com
DIRECT DIAL (973) 315-4538

May 8, 2008

By Facsimile
Honorable Frank Maas
United States Magistrate Judge
Daniel Patrick Moynihan
United States Courthouse
500 Pearl St., Room 740
New York, NY 10007

Re: AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.
07 Civ. 6790 (CM)(FM)

Dear Judge Maas:

We represent defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. ("DRL") in the above matter. We write to obtain Your Honor's help in expediting our production of certain limited discovery to the AstraZeneca defendants in accord with Judge McMahon's Rulings On AstraZeneca's Request For Infringement Discovery, copy attached. In particular, DRL asks Your Honor to order AstraZeneca to receive the discovery pursuant to the confidentiality agreement that has been operative in this case since last October. The details of that operative agreement are reiterated in a May 6, 2008 letter from Louis H. Weinstein to Errol B. Taylor, copy attached. AstraZeneca is not willing to abide by that agreement. In particular, AstraZeneca is not willing to limit its use of DRL's confidential information to the question of determining whether DRL infringes the patents-in-suit.

By way of background, DRL has maintained from the start of this litigation that AstraZeneca has no evidence to support a claim that DRL's proposed product infringes the patents-in-suit. On September 19, 2007 counsel for DRL wrote to Judge McMahon suggesting that the issues in this case could be narrowed most expeditiously if DRL filed an early motion for summary judgment. At the September 21, 2007 Initial Pretrial Conference Judge McMahon directed the parties to assume that DRL had made its motion. The Court ordered DRL to produce samples by September 24, 2007 and AstraZeneca was ordered to test these samples by November 1, 2007. DRL produced its samples and DRL responded to AstraZeneca's interrogatories.

At the November 7, 2007 Conference AstraZeneca reported that it had tested DRL's samples and that AstraZeneca still had no evidence of infringement. The Court gave AstraZeneca 10 days to submit a brief detailing the additional discovery that it

sought and explaining exactly why it was needed. AstraZeneca submitted its brief to the Court on November 19. DRL submitted its response on November 28. In its papers DRL objected to all of the requested discovery, DRL explained why the requested discovery could not support a claim for patent infringement, and DRL asked the Court to grant DRL summary judgment.

Judge McMahon has since ruled that "AstraZeneca's discovery requests smack of a fishing expedition." Rulings On AstraZeneca's Request For Infringement Discovery, at Par. (2). Nonetheless, Judge McMahon did order "some modest additional discovery." *Id.* at Par. (3). At the conclusion of this discovery, which is presently set for May 23rd, 2008, AstraZeneca "will have 30 days to decide whether to withdraw the instant action," and if not, DRL "will have 30 days to move for summary judgment." *Id.* at Par. (9).

DRL is prepared to promptly produce the documents called for in the additional discovery on the condition that AstraZeneca will abide by the confidentiality agreement under which DRL has already produced confidential information to AstraZeneca. *See* May 6, 2008 letter from Louis H. Weinstein to Errol B. Taylor. Unfortunately, AstraZeneca is not willing to abide by the existing agreement. In particular, AstraZeneca will not limit its use of DRL's confidential information to the question of determining whether DRL's proposed product infringes the two-patents-in-suit. DRL respectfully asks Your Honor to preserve the status quo and to order AstraZeneca to receive the additional discovery pursuant to the conditions of the existing agreement, as detailed in the attached letter of May 6.

As detailed in the attached letter, the existing agreement allows AstraZeneca to disclose DRL's confidential information and the information derived therefrom to a large but specified group of attorneys, client representatives, AstraZenca scientists and outside experts. The existing agreement further requires that these persons will continue to not be involved in patent prosecution. Finally, the existing agreement requires that DRL's confidential information and the information derived therefrom will only be used to determine whether DRL infringes the two patents-in-suit.

AstraZeneca has told DRL that it wants DRL to produce the documents called for in Judge McMahon's Ruling by tomorrow. AstraZeneca can have those documents as soon as it agrees to abide by the existing confidentiality agreement. The only information being produced at this time is DRL's confidential information and DRL sees no need for the unusually complicated protective order, copy attached, proposed by AstraZeneca to DRL after the close of business yesterday. That proposed protective is based on the facts of a different case. As Your Honor knows, protective orders are tailored to the facts of

particular cases and are often the subject of protracted negotiations. We see no reason why the facts and circumstances prevailing in another case should control the disclosure of confidential information here, nor do we think that Judge McMahon intended that the parties change their existing confidentiality agreement or engage in protracted negotiations.

Accordingly, DRL respectfully asks Your Honor to order AstraZeneca to accept the limited discovery ordered by Judge McMahon according to the requirements detailed in the attached May 6 letter. If AstraZeneca chooses not to drop this action and it survives summary judgment, the parties can then negotiate a more complicated protective order of the type proposed by AstraZeneca, if and when a more complicated protective order is needed.

Finally, DRL takes this opportunity to inform Your Honor of a potential glitch in complying with Judge McMahon's order that the deposition of the single DRL witness be completed by May 23, 2008. The appropriate witness will in all likelihood be an Indian national currently located in India. DRL is identifying the appropriate witness and ascertaining the witness's visa status and travel arrangements. Because of visa issues out of DRL's control it will probably not be possible to bring that witness to the United States in time to conduct the deposition before May 23. DRL has offered to produce the witness in India before May 23 or in the undersigned counsel's Short Hills, New Jersey offices as soon as possible. We will keep counsel for AstraZeneca and Your Honor apprised of this issue.

Respectfully submitted,

Louis H. Weinstein

Enclosures
cc: Counsel for AstraZeneca/by facsimile
Hon. Colleen McMahon/by facsimile
676922

EXHIBIT 29

MILBANK, TWEED, HADLEY & McCLOY LLP

1 CHASE MANHATTAN PLAZA

NEW YORK, N.Y. 10005-1413

212-530-5000

FAX: 212-530-5219

LOS ANGELES
213-892-4000
FAX: 213-629-5063

WASHINGTON, D.C.
202-835-7500
FAX: 202-835-7586

LONDON
020-7615-3000
FAX: 020-7615-3100

FRANKFURT
49-69-71914-3400
FAX: 49-69-71914-3500

MUNICH
49-89-25559-3600
FAX: 49-89-25559-3700

BEIJING
8610-5123-5120
FAX: 8610-5123-5191

HONG KONG
852-2971-4888
FAX: 852-2840-0792

SINGAPORE
65-6428-2400
FAX: 65-6428-2500

TOKYO
813-3504-1050
FAX: 813-3595-2790

JOHN M. GRIEM, JR.
PARTNER
DIRECT DIAL NUMBER
212-530-5429
FAX: 212-822-5429
E-MAIL: jgriem@milbank.com

May 9, 2008

VIA FACSIMILE
Hon. Frank Maas
United States Magistrate Judge
Daniel Patrick Moynihan
United States Courthouse
500 Pearl St., Room 740
New York, NY 10007

Re: *AstraZeneca AB, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*
07-civ-6790 (CM)(FM)

Dear Judge Maas:

We represent plaintiffs AstraZeneca AB, et al. ("AstraZeneca") in the above matter. We write in response to DRL's May 8, 2008 letter regarding the treatment of discovery materials.

The current dispute between AstraZeneca and DRL stems from DRL's proposal to limit AstraZeneca's use of information DRL may provide to AstraZeneca in accordance with Judge McMahon's "Rulings on AstraZeneca's Request for Infringement Discovery." In its May 6, 2008 letter to AstraZeneca, DRL requested that AstraZeneca agree only to use the produced information to determine whether DRL infringes the two patents-in-suit. In response, AstraZeneca proposed a protective order governing the use of confidential discovery materials which is substantively identical to the protective order in place in other similar patent litigations between the parties. AstraZeneca used this form because DRL was familiar with its contents and therefore the negotiations over the terms of the protective order could be expedited.

The background of this case strongly supports not only AstraZeneca's need for discovery, but also permitting AstraZeneca broader use of discovery information than DRL's proposal. This is a case arising under the Hatch-Waxman Act, 35 U.S.C. § 271(e) and 21 U.S.C. §355(j). DRL submitted an Abbreviated New Drug Application ("ANDA") to the Food and

Drug Administration ("FDA") seeking approval to manufacture, import and sell a generic equivalent of AstraZeneca's Prilosec OTC® before the expiration of AstraZeneca's patents. In a letter dated June 13, 2007, DRL notified AstraZeneca that it intended to market its product and asserted that it provided the FDA with data purporting to show that its product is bioequivalent to AstraZeneca's patented product. In the same letter, DRL made conclusory statements that its product will not infringe the two patents-in-suit, but provided no details of its analysis.

Upon receiving the June 13 letter, AstraZeneca made limited requests for information and samples from DRL to confirm that its product conformed with the claims made in its letter. After failing to obtain all of the necessary information and samples, AstraZeneca filed suit on two of the patents DRL alleged were not infringed by its product, in part to obtain the information necessary to determine whether DRL's product was consistent with the claims made in DRL's June 13 letter. *See Hoffman–LaRoche*, 213 F.3d 1359, 1363-65 (Fed. Cir. 2000) (reasonable to move forward with infringement litigation upon reasonable but unsuccessful inquiry). In the Discovery Rulings, Judge McMahon agreed that AstraZeneca is entitled to examine the documents DRL submitted to the FDA in support of its ANDA.

AstraZeneca's modest discovery requests throughout the litigation are far from a fishing expedition. At all points, AstraZeneca sought only the information necessary to assess infringement and whether the allegations in DRL's June 13 letter were accurate. To date, DRL has only provided self-selected portions of its FDA filings, single samples of its active ingredient and final product, and answers to 10 interrogatories. From this information, AstraZeneca has been unable to evaluate whether the samples produced are representative of DRL's product, and whether the product infringes the patents-in-suit. If DRL's product infringes during manufacture, it may infringe AstraZeneca's patents even if the material is changed before importation. *See* 35 U.S.C. § 271(g).

DRL's proposed May 6 letter agreement is unduly restrictive and incomplete. The agreement does not even allow AstraZeneca to assess all of the claims made in its complaint, in particular that DRL's June 13 letter failed to meet the statutory notice letter requirements as specified in 21 U.S.C. §355(j), and FDA rules and regulations, as specified in 21 C.F.R. § 314.95. (Complaint at ¶17-23, 37-43). Nor does it allow for use of information which is public or may become public and provides no avenue for AstraZeneca to challenge improper confidentiality designations. It also does not allow for use of the produced information with a deponent or others who may have had access to the information. This is especially inappropriate because DRL is due to produce a witness with knowledge of its manufacturing process for a deposition in accordance with Judge McMahon's Discovery Rulings. Additionally, DRL's proposal does not address the handling of the transcript of the upcoming deposition that may involve the use of protected materials. The protective order would address these concerns.

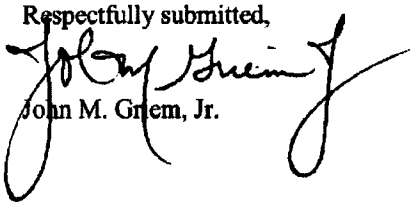
AstraZeneca's proposed protective order includes other protections that DRL's proposal does not, such as the return of inadvertently produced privileged information, and the ability to designate as protected materials that were unintentionally disclosed. (Par. 9 of proposed order). The protective order outlines the procedure for filing protected materials with the Court. (Par. 11 of proposed order). It also prescribes the handling of confidential information at the conclusion of the action. (Par. 12 of proposed order).

Other than the dispute with respect to use of protected information, AstraZeneca is not aware of any specific DRL objection to the proposed protective order. AstraZeneca is willing to limit disclosure of discovery information to the individuals listed in DRL's May 6, 2008 letter. It also agrees to DRL's condition that the persons with access to confidential information not be involved in the prosecution of patents relating to omeprazole. Both of these restrictions are addressed in Paragraph 4 of the proposed protective order.

DRL's proposed limitation to use discovery information solely for the purpose of determining whether DRL infringes the patents-in-suit is contrary to law. AstraZeneca should be able to use the information for any purpose usually permitted in connection with discovery produced during litigation, such as considering whether to amend its complaint. *See Riordan v. Nationwide Mut. Fire. Ins. Co.*, 756 F.Supp. 731, 737 (S.D.N.Y. 1990) (plaintiff's claims can be amended based on information obtained during discovery); *see also Semitool, Inc. v. Tokyo Electron America, Inc.*, 208 F.R.D. 273 (N.D.Cal. 2002) (complaint can be amended to add other patents based on information about allegedly infringing device obtained in discovery that plaintiff had no prior access to). DRL has not shown that it will be prejudiced by this forseeable use of discovery information. AstraZeneca is hamstrung in this case because it has not had an adequate opportunity to test the potentially self-serving claims made in DRL's June 13 letter.

Accordingly, AstraZeneca respectfully asks Your Honor to consider the proposed protective order and the use of discovery information therein and to direct that the parties enter into the protective order. In addition, AstraZeneca respectfully asks Your Honor to order that DRL produce the required information as soon as possible.

Respectfully submitted,



John M. Gnem, Jr.

cc: Louis H. Weinstein, Esq.
Michael Imbacuan, Esq.
Counsel for Defendants Dr. Reddy's Laboratories, Ltd., et al. (via facsimile)
Hon. Colleen McMahon

EXHIBIT 30

From: "Griem, Jack" <JGriem@milbank.com>
To: "Louis Weinstein" <lweinstein@budd-larner.com>
Date: 5/13/2008 3:38:30 PM
Subject: RE: Astra v DRL Omep mg

Lou

Further to our calls today, AstraZeneca will accept the documents subject to your May 6 letter restrictions, while reserving the right to raise the appropriateness of the restrictions and other issues briefed with Judge Maas with a new magistrate or Judge McMahon. Please have the documents sent to my attention.

We will take the deposition at your Short Hills office on May 23. Please let us know the name and title of the person who will be produced.

Jack.

Milbank
Intellectual Property/Litigation
John M. Griem, Jr.
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T: 212-530-5429 F: 212-822-5429
jgriem@milbank.com
www.milbank.com

-----Original Message-----
From: Louis Weinstein [mailto:lweinstein@budd-larner.com]
Sent: Monday, May 12, 2008 7:28 PM
To: Griem, Jack
Cc: Louis Weinstein
Subject: Astra v DRL Omep mg

Jack
I am out of state till late Tuesday night but I am making arrangements to have DRL's production shipped out of our office on Tuesday for overnight delivery.

We are also making arrangements to produce DRL's witness for deposition in our Short Hills office on May 23. Please confirm ASAP that you will take the deposition that date in our Short Hills office because plane tickets from India need to be purchased forthwith and other travel arrangements need to be made.

Kindly confirm your receipt of this e-mail.

Regards
Lou

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EXHIBIT 31

From: "Griem, Jack" <JGriem@milbank.com>
To: "Louis Weinstein" <lweinstein@budd-larner.com>
Date: 5/19/2008 5:20:50 PM
Subject: RE: AstraZeneca v. Dr. Reddy's Labs. Ltd, 07 Civ. 6790(CM)(FM)

Try me at 5:30 pm. The number is 212 530 5429.

-----Original Message-----
From: Louis Weinstein [mailto:lweinstein@budd-larner.com]
Sent: Monday, May 19, 2008 5:12 PM
To: Griem, Jack
Cc: Louis Weinstein
Subject: Re: AstraZeneca v. Dr. Reddy's Labs. Ltd, 07 Civ. 6790(CM)(FM)

Jack
I am available to talk any time after 5:20 this evening

Please let me know when I can call you and the number I should call.

Lou
-----Original Message-----
From: "Griem, Jack" <JGriem@milbank.com>
To: Louis Weinstein <lweinstein@budd-larner.com>
Cc: Errol Taylor <ETaylor@milbank.com>

Sent: 5/16/2008 4:48:15 PM
Subject: AstraZeneca v. Dr. Reddy's Labs. Ltd, 07 Civ. 6790 (CM)(FM)

Dear Lou:

It appears that DRL's ANDA and DMF production is incomplete, based on our review to date. The court ordered DRL to produce "full and entire versions of the ANDA paperwork and the DMF files that were submitted by DRL to the Food and Drug Administration."

Regarding the ANDA, it appears the documents produced do not include sections I-VI, or any correspondence related to the original submission of the ANDA. The production begins at DRL 00001 with Section VII. Please immediately produce the rest of the ANDA. In addition, we note there appear to be problems with the portions of the ANDA that were produced. We have located two minor amendments submitted to the FDA in the ANDA, dated December 4, 2007 (DRL 02624-02933) and April 29, 2008 (DRL 02934-02971). These amendments appear incomplete, in that they do not contain complete copies of Form FDA 356h (in each case, only 2 of 5 pages is provided) and they do not contain any narrative response to the FDA's deficiencies identified in the FDA corespondence included in each minor amendment as Exhibit 1. We would expect a letter from DRL directly addressing each of the listed deficiencies. Also, please confirm that we have received all correspondence with the FDA relating to the ANDA. Specifically, please confirm there is no ANDA correspondence either to or from the FDA after the minor amendment submitted April 29, 2008.

Regarding the DMF (DRL 02972-03674), it appears that an updated copy was provided, but not a chronological record of all communication with the FDA regarding the DMF. Please immediately produce an entire, complete

copy of the original DMF submission, plus all subsequent correspondence,

including all annual reports.

Also, please immediately produce any binders of data or other supporting documents submitted to the FDA in connection with the ANDA or the DMF.

Jack Griem.

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==========

EXHIBIT 32

From: "Louis Weinstein" <lweinstein@budd-larner.com>
To: <JGriem@milbank.com>
Date: 5/20/2008 5:33:05 PM
Subject: Astra v. DRL (Omep Mg)

Jack:

Thank you for speaking with us yesterday and today. Pursuant to the agreement reached as a result of those calls, i.e., that the production of the attached would resolve all discovery disputes in advance of the May 23rd deposition, enclosed please find PDF files corresponding to DRL 03648-03871.

We look forward to seeing you at 7:30 on the 23rd.

Lou